



DEPARTMENT OF NATURAL RESOURCES

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Re: U.S. Environmental Protection Agency's (EPA) October 17, 2005, Comment Letter on the Draft Departmental Missouri Risk-Based Corrective Action (MRBCA) Technical Guidance Document

Dear Mr. Spratlin and Ms. Tapia:

We reviewed your comments and offer the following responses to help clarify our views regarding issues raised in your letter. I hope that these responses will help ease EPA's technical concerns regarding use of the MRBCA process. I look forward to resolving these concerns to move forward and finalize our guidance soon. Our responses address both general issues as well as the more specific issues addressed in your letter.

We will continue discussions regarding the applicability of the MRBCA process to many sites in Missouri. Given EPA's One Clean-up Program Initiative and the nearly identical risk assessment equations of the MRBCA and RAGS processes, we have difficulty understanding why there is so much concern regarding relatively minor changes in just a few default assumptions and calculation of certain risk assessment equation input parameters. Our process is based on defensible science and appropriate conservatism that provides for adequate protection of human health and the environment while streamlining the overall investigation and remediation processes. This facilitates development and reuse of more sites.

Adequate site characterization is absolutely critical to use of any risk-based corrective action process. Several sections of the MRBCA document speak to the issue of site characterization. In particular, Sections 2.2.3., 5.0 and 6.0 of the MRBCA document discuss the extent of



conceptual model development and release characterization that may be required in site-specific circumstances. As written, extent of contamination determinations may be required to Default Target Levels (DTLs) at many sites. This methodology would essentially be analogous to characterizing releases to the lowest EPA Region IX Preliminary Remediation Goal (PRG) for each affected media. The MRBCA document does, however, retain flexibility to consider site-specific circumstances and potential exposure pathways when developing target investigation levels. This is an important aspect as characterization to DTLs may not be necessary or appropriate at each and every site.

This guidance is intended to emphasize a process rather than deal with every particular answer to every question. MRBCA is not a comprehensive and complete guidance tool for every aspect of managing a hazardous waste site. Our project managers and the remediating parties will identify additional, relevant guidance.

Concerns were raised regarding calculation of exposure point concentrations and the potential of the averaging method and the possibility to underestimate potential risks for the exposure point concentrations. This issue was carefully considered during our discussions and decision-making. We agree that further clarification of exposure domain in the MRBCA document is needed as evidenced by the example provided as Figure 1.

The exposure domain is synonymous with the area(s) of impact. In your example, the sampling points falling outside the highlighted impacted areas in Figure 1 would not be used in determining the average representative concentration for that exposure domain. Only those areas impacted by releases would be included. This creates a conservative average similar to using a 95% Upper Confidence Limit (UCL) approach. We are very concerned that any contaminant concentration averages used for risk assessment purposes not be artificially diluted by inclusion of non-detectable concentrations that might result from a broader definition of exposure domain. We absolutely do not want facilities skewing their sampling to produce artificially low average contaminant concentrations. Factors to be considered in the calculation of representative concentrations for risk assessment purposes are discussed in detail in Appendix C. Additional safeguards against the inappropriate use of average concentrations are in Section 8.8, Alternative 1, Condition 2; Section 9.5, Alternative 1, Condition 2, and Section 10.6, Alternative 1, Condition 2. For clarity, it may be useful to include a discussion of these safeguards in other sections of the MRBCA document and to ensure that ample references to Appendix C are also provided throughout the main text of the document.

The MRBCA guidance does not focus solely on the use of arithmetic average contaminant concentrations within impacted areas for risk assessment purposes. Arithmetic averages may be more appropriate under certain circumstances, such as, if uniform grid sampling is used across an area of impact. If biased sampling is conducted within an area of impact, use of a weighted average may be more appropriate. We recognize there are several approaches that may be used

to calculate such averages. The MRBCA document retains flexibility regarding averaging and these approaches are discussed in detail in Appendix C.

We do not understand your ongoing concerns related to site-specific evaluation of vapor intrusion given our previous detailed responses. We are clearly not focusing our efforts solely on predictive modeling and measurement of contaminants in soil vapor as a means to evaluate potential impacts to indoor air. These are certainly two approaches, but we are also committed to looking at both sub-slab and/or indoor air sampling, when appropriate, in the evaluation of vapor intrusion as warranted by site-specific conditions.

It is our understanding that EPA is currently revising the 2002 draft vapor intrusion guidance. We understand that this revision stems from real world experiences where the draft guidance has been overly conservative in screening many sites for potential vapor intrusion problems. Depending upon the outcome of EPA's revision, the differences in the MRBCA screening values as compared to those in EPA's revised guidance may be greatly reduced. We generally support the tiered, step-by-step approach to evaluation of vapor intrusion as contained in EPA's 2002 guidance. The reference to the most current version of EPA's vapor intrusion guidance will be cited in the MRBCA document. We also support EPA's recent policy regarding the applicability of Occupational Safety and Health Administration versus EPA requirements in the assessment of indoor air issues at industrial or commercial facilities and will reference that policy in the MRBCA document as well.

We generally agree with EPA's approach for evaluation of vapor intrusion. However, certain elements are lacking in EPA's existing guidance. Therefore, soil gas sampling protocols were incorporated into the draft MRBCA guidance. This supplemental information is not an attempt to shift the focus towards soil gas evaluation in lieu of other methodologies. We assume that EPA's ongoing concern may be that Section 6.14 and Appendix H of the draft MRBCA document have not been revised to incorporate our responses to your comments on the vapor intrusion issues. Our acknowledgement of predictive modeling and the addition of supplemental information on soil gas sampling in the draft MRBCA document, may have been misperceived by EPA as favoring only those evaluative methods. We will try to eliminate any potential misperceptions as Section 6.14 and Appendix H are revised.

If EPA is having difficulty following certain aspects of the MRBCA guidance document, then the stakeholders using it will too. We need to maintain consistency throughout the MRBCA document with respect to site characterization, development of conceptual site models and calculation of exposure point concentrations for risk assessment purposes. Any further comments regarding inconsistencies in the document and recommendations for clarification are welcome.

We agree to exclude proposed and final National Priority List (NPL) sites from the MRBCA process and expect that this exclusion will be documented in the Memorandum of Agreement (MOA) on the use of MRBCA. If, after consideration of the information provided by this

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correspondence, EPA continues to believe that the MRBCA process cannot be used at RCRA permitted or order sites, we are proposing to temporarily table these discussions until all of EPA's issues have been raised, including any issues from EPA Headquarters that may be identified as part of the MOA approval process. We suggest that terms in the MOA acknowledge the applicability of the MRBCA process to RCRA expedited corrective action sites not under a permit or order. In addition, it is our intention that the MOA include provisions to ensure that discussions will continue between the state and EPA to resolve the remaining issues and applicability of the MRBCA guidance document to all RCRA corrective action sites. Please let us know as soon as possible when EPA Headquarters provides comments concerning the draft MOA so that we can address those comments and finalize the MOA.

The EPA has been an MRBCA Work Group stakeholder for several years and has had numerous different staff present at various MRBCA meetings. The EPA staff also intermittently participated on some of the MRBCA subgroups. However, we are disappointed that EPA chose not to participate actively and consistently through all the MRBCA development process. Many of the challenges we now face to resolve EPA's concerns may have been avoided. Department staff have worked since the inception of the MRBCA development process to engage and inform EPA staff. Interactive, ongoing dialog throughout the development process decreases the resolution of issues at the end. This applies to the discussions between our two agencies, and to the discussions between EPA, Region VII, and EPA Headquarters. It is frustrating to receive comments from several directions on a regional level, only to have those overridden by headquarters when we've sought to follow an open collaborative process. We strongly encourage EPA to stay actively engaged in this process as the MRBCA is finalized.

We look forward to completing our guidance soon. If you have any questions, please do not hesitate to contact me.

Sincerely,

HAZARDOUS WASTE PROGRAM

Original signed by Robert Geller

Robert Geller
Director

RG:rnj

Enclosure

**Responses to EPA's Comment Letter on the Draft
Departmental Missouri Risk-Based Corrective Action (MRBCA)
Technical Guidance Document**

1) Exposure Point Concentration:

We carefully considered this issue during development of the MRBCA guidance. As indicated above, we believe that EPA may have misunderstood certain areas of our expectations for defining the extent of environmental impacts, the area(s) over which averages would be calculated, the types of averages that might need to be calculated, and the safeguards that are in place to ensure that use of averages does not compromise our ability to make informed, well-supported decisions regarding protection of human health and the environment.

By using averages in concert with adequate site characterization and secondary safeguards, we hope to simplify and streamline certain aspects of the risk-assessment process as compared to using 95% UCLs. As an example, we ran the ProUCL software to estimate the 95% UCL for the data presented in your example. The software yielded 12 values for the 95% UCL ranging from approximately 946 mg/kg to 89,201 mg/kg. The software recommended use of a 99% Chebyshev's method value of 3426 mg/kg. This simple example highlights the difficulties that we often face with respect to use of 95% UCLs and why we have proposed adoption of an "averaging" approach with accompanying safeguards/controls. In this example, we are faced with having to rationalize which of the 12 values to use and, if we accept the software recommendations, explain why a 99% UCL (an even more conservative scenario) is needed when EPA's guidance generally says to use 95%. These are the types of situations we hope to avoid through judicious use of averages.

The MRBCA process strives to accurately and reasonably represent risks. We do not believe that a particular risk assessment process is superior simply because it arrives at a more conservative risk-based decision. While the EPA may be able to demonstrate that an EPA risk-based input value or screening number may be lower or more conservative than a state value, it does not follow that a more conservative value results in a better assessment of risk. We believe that risk assessment inputs should result in a more accurate (but not necessarily more conservative) assessment of risk that will, in turn, result in a better risk-based decision-making.

2) Exposure Variables

We understand that EPA operates on the premise of reasonable maximum exposure scenarios as contained in EPA guidance. We reiterate our belief that the MRBCA process employs use of reasonable maximum exposure scenarios, recognizing that "reasonable" is a judgement call upon which the state and the EPA may differ to some degree. Some examples of these differences are highlighted below.

Our construction worker soil ingestion rate is 100 mg/day and the EPA default value is 331 mg/day. In a study entitled "Soil Ingestion in Adults – Results of a Second Pilot Study," the conclusion of the authors was that the median soil ingestion rate for adults was 1 mg/day, the

75th percentile ingestion amount was 49 mg/day, and the 95th percentile soil ingestion estimates were 331 mg/day. The study also concluded that the average soil ingestion rate was 10 mg/day.

Therefore, our default rate is between the 75th percentile and the 95th percentile (the latter value in agreement with that used by the EPA). Because of the extreme variability from median to 95th percentile, the authors conclude that, “In the judgement of the authors, estimates based on the median of the best four trace elements are most likely to be best.... The 95th percentile soil ingestion estimate was 331 mg/day, but based on present data, it is substantially uncertain.”

We also quote from the EPA publication, “Exposure Factors Handbook,” which states, “In the past, many EPA risk assessments have assumed an adult soil ingestion rate of 50 mg/day for industrial settings and 100 mg/day for residential and agricultural scenarios. These values are within the range of estimates from the studies discussed above. Thus, 50 mg/day still represents a reasonable central estimate of adult soil ingestion and is the recommended value in this handbook. This recommendation is clearly highly uncertain; however, and as indicated in Table 4-21, is given a low confidence rating. Considering the uncertainties in the central estimate, a recommendation for an upper percentile value would be inappropriate.”

Please note that the MRBCA default value for the non-residential worker is 100 mg/day. Based upon the information cited above, the department believes this value to be both conservative and considerably higher than a reasonable maximum. Based on the foregoing sources, a value of 49-50 mg/day actually appears to be sufficiently conservative as a reasonable maximum in the assessment of risks to non-residential workers.

The EPA states that the MRBCA daily inhalation rates are 1.3 to 4 fold less than those used in risk assessment by EPA. We do not understand why EPA has chosen to continue to raise this issue inasmuch as we have already agreed to revise these rates. In our last correspondence with you (as posted on our public website in August) and as discussed in our August 23, 2005, meeting, we proposed revision of the daily inhalation rate for a construction worker to 1.8 m³/hr (18 m³/day based on a 10 hour construction work day), which is only slightly less than EPA’s recommended value of 20 m³/day for an adult. We continue to stress that we believe we provide both ample flexibility and more realism in the assessment of inhalation risks by focusing on hourly, as opposed to daily inhalation rates. We do not believe it is “reasonable” to assume that individuals remain in the same location 24 hours a day, 350 days a year for 30 years while breathing at some defined universal daily rate. While daily overall breathing volumes for children and adults may well be in line with EPA default assumptions, we believe that the risk assessment process should provide flexibility to consider and address activity-specific breathing rates in the production of a more accurate assessment of risk.

We believe our proposed dermal exposure variables are consistent with EPA’s recently finalized RAGS Part E Dermal Exposure Guidance. As you know, we agreed in our last correspondence with you to use RAGS Part E guidance in lieu of EPA’s previous RAGS Part A guidance in the assessment of risks from dermal exposure.

3) Vapor Intrusion

The MRBCA Tier 1 groundwater risk-based screening values are land-use and soil dependent. For example, the MRBCA residential screening values (1×10^{-5} incremental excess lifetime cancer risk, HI = 1.0) for trichloroethylene (TCE) range from 1,600 ug/l in sandy soil to 4,490 ug/l in clay soil. Similarly, in non-residential settings, the screening values (1×10^{-5} incremental excess lifetime cancer risk, HI = 1.0) for TCE range from 8,410 ug/l in sandy soil to 23,600 ug/l in clay soil. EPA's screening value (1×10^{-5} incremental excess lifetime cancer risk, HI = 1.0) for volatilization of TCE from groundwater to indoor air is an MCL-based 5.0 ug/l, rather than a calculated land use/soil-type based concentration. Obviously, there are differences in the way that the screening values were derived. Rather than utilizing standard, across the board default assumptions in developing a single number, the MRBCA process attempts to bracket the range of conditions that may be encountered at sites thereby enabling better site-specific screening without requiring facilities to initially do any calculations. This approach seems to be advocated within the context of EPA's vapor intrusion guidance, albeit at a higher tier. We have simply tried to streamline the screening process by providing a ready source of higher-tiered information rather than causing each facility to do site-specific screening level calculations.

Due to the highly technical nature of the equations used to calculate volatilization from groundwater to indoor air, the number of variables involved in the calculations and EPA's use of empirically-derived attenuation factors, we are having some difficulty contrasting and comparing the methodology use to calculate the MRBCA groundwater to indoor air screening concentrations versus those contained in EPA's draft vapor intrusion guidance. It is currently unclear to us where all the differences lie between the MRBCA calculation methodology for indoor air screening values and that used to derive the values contained in EPA's vapor intrusion guidance. We also do not know if EPA's current efforts to revise the vapor intrusion guidance at the national level will result in any changes to the manner in which EPA derives groundwater to indoor air screening concentrations. We feel that these differences and any impending changes need to be more clearly understood before we can completely resolve this issue. We suggest that our technical staffs, perhaps with assistance from RAM Group, work together to clearly identify the specific elements/input parameters which are causing the disparity in the screening concentrations. We would also appreciate any information that EPA can provide with respect to impending changes in EPA's vapor intrusion guidance that may affect resolution of this issue. Once we clearly understand the differences and any impending changes, we should have the basis to either resolve the differences/issues or agree to disagree.

4) More accurate portrayal of cumulative risk

Our methodology for calculation of cumulative risks is not in question; therefore, we understand your comment to mean that you want the state to require calculation of cumulative risk at sites utilizing the MRBCA process, including those with few chemical constituents of concern. We would appreciate clarification as to whether this comment is directed at each and every site utilizing MRBCA or is directed specifically towards risk assessment activities at CERCLA and/or RCRA corrective action facilities due to federal "equivalency" or "consistency" concerns.

This information will help us to fashion any clarifying language that may be needed in the MRBCA guidance document, the associated rules and/or MOA.

You have expressed that cumulative risk should always be calculated irrespective of the number of site-specific chemical constituents of concern with the objective of making sure that the risk assessment conclusions, including the cumulative risk posed by a site, are as transparent and understandable as possible. We certainly agree that the administrative record used to support environmental decision-making should be clear and comprehensive. As you know, our original objective in not requiring the calculation of cumulative risk at sites with 10 constituents of concern or less was to streamline the risk assessment process in situations where exceedance of the cumulative incremental excess cancer risk threshold of 1×10^{-4} is mathematically impossible. That said, we do not disagree with EPA's observation that, for public participation purposes, it would be clearer if the cumulative risk were calculated. At this time, there is a detailed discussion of this calculation in the MRBCA document and it is left to the discretion of individual project managers to require their facilities to calculate cumulative risk or, if they choose, independently perform such calculations, as appropriate.

We clearly recognize that the calculation of cumulative risk is relatively straightforward and would not be unduly burdensome and have conveyed this point to the larger MRBCA stakeholder group on several occasions. Nevertheless, we continue to encounter substantial resistance from some stakeholders in making calculation of cumulative risk mandatory at every site. To date, the reasons given for this resistance are that it would require additional effort on the part of facilities and is not "technically" necessary given the 10 constituents of concern or less "threshold" governing the cumulative risk calculation. Please understand that many of the stakeholders involved in the MRBCA development process appear to have little, if any, interest in the public participation aspects of the remedy selection process, which may further explain their resistance to doing anything they view as extraneous. We intend to continue to discuss this element of the MRBCA process with the stakeholders and will retain, at a minimum, our ability to independently calculate cumulative risk, as appropriate. If your concerns are specifically directed at this issue as it applies to CERCLA and RCRA corrective action facilities, perhaps we could include language in the MOA to mitigate your concerns by acknowledging that cumulative risk would be calculated at all such sites whether by the facility or the department. .

References:

U.S. Environmental Protection Agency. Exposure Factors Handbook, August 1997.

Stanek, Edward J. III, Edward J. Calabrese, Ramon Barnes and Penelope Pekow. "Soil Ingestion in Adults: Results of a Second Pilot Study" *Ecotoxicology and Environmental Safety*, Volume 36, Issue 3, April 1997, pages 245-257.